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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,736	09/21/2006	Claudia Bedard	BED001	7789
27137 7590 03/17/2009 DIEDERIKS & WHITELAW, PLC 12471 DILLINGHAM SQUARE, #301 WOODBIDGE, VA 22192				
EXAMINER MCKANE, ELIZABETH L.				
ART UNIT		PAPER NUMBER		
1797				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/553,736

**Applicant(s)**

BEDARD ET AL.

**Examiner**

ELIZABETH L. MCKANE

**Art Unit**

1797

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-10 and 12-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-10, 12-15, 17 and 18 is/are allowed.
- 6) ☒ Claim(s) 1 and 3-5 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable Robitaille et al. (US 2002/0085950) in view of Childers et al. (US 5,527,508).

Claim 1 is written in Jepson claim format, which is an admission that the limitations recited in the preamble up to the phrase "the improvement comprising," are considered to be known prior art. In any event, Robitaille et al. teaches essentially the claimed method wherein an article to be sterilized may be exposed to repeated cycles of a vacuum (0.5-2 mbar) followed by humidified ozone. See Figure 3; paragraphs [0013]-[0032]. The sterilization chamber is maintained at a temperature of 20-35 °C (paragraph [0053]). Robitaille et al. further discloses that "the high relative humidity level combined with temperature differentials between walls and/or the load may lead to water condensation." See paragraph [0039]. Robitaille et al. is silent with respect to removing condensation during the sterilization cycle between successive exposures to the humidified ozone.

Childers et al. discloses a method of gaseous sterilization including repeated cycles of a vacuum, injection of a sterilant, and injection of an inert gas. See col.6, lines 14-30. The injection of an inert gas into the chamber drives the sterilant vapor into closed or open ended lumens while the step of drawing a vacuum removes residual

sterilant vapors and humidity, thus preparing the system for the next sterilization pulse.  
See col.6, lines 57-62.

It would have been obvious to one of ordinary skill in the art to inject or "flush" the sterilization chamber of Robitaille et al. with an inert gas, as disclosed by Childers et al. in order to drive the sterilant vapor into the lumens of instruments sterilized by Robitaille et al.. Note that Robitaille et al. discloses the sterilization of endoscopes, which are lumened instruments.

As to claim 3, Childers et al. teaches that an inert gas or air can be used to "flush" the chamber. Nevertheless, as Robitaille et al. already discloses a method of removing humidity at the end of the sterilization cycle by flushing with repeated pulses of oxygen (paragraph [061]), it would have been obvious to use this same gas for driving the sterilant vapor in the combination of Robitaille et al. with Childers et al..

With respect to claim 4, it is deemed well-within the purview of one of ordinary skill in the art to repeat the flushing step in order to assure complete penetration of the sterilant into lumens.

As to claims 5, Robitaille et al. discloses temperature equalization at the beginning of the sterilization process but not between cycles. See paragraph [0030]. However, as Robitaille et al. also teaches that temperature differentials are a cause of water condensation (paragraph [0039]), it would have yielded predictable results to also equalize the temperature between cycles as a further means of reducing water condensation.

***Allowable Subject Matter***

3. Claims 6-10, 12-15, 17, and 18 are allowed.
4. Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

5. Applicant's arguments filed 8 December 2008, with respect to claims 1 and 3-5, have been fully considered but they are not persuasive.
6. On page 8 of the Response, Applicant argues that "it is only after the removal of a sterilant and after a further evacuation to remove the sterilant that the gas is introduced" for flushing. However, it is noted that this particular arrangement of steps is not required by claim 1.

***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH L. MCKANE whose telephone number is (571)272-1275. The examiner can normally be reached on Mon-Fri; 5:30 a.m. - 2:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/  
Primary Examiner, Art Unit 1797

elm  
16 March 2009